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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,994	07/14/2003	Scott Cunningham	2848	5963
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EXAMINER YABUT, DIANE D				
ART UNIT 3734		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/618,994

Applicant(s)

CUNNINGHAM ET AL.

Examiner

DIANE YABUT

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-17 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-17 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This action is in response to applicant's amendment received on 02/28/2008.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims rejected 1-2, 5-7, 10, 12-14, and 21-22 are rejected under 35 U.S.C.

103(a) as being unpatentable over **Prasad** (U.S. Patent No. **5,330,441**) in view of **Otsuka** (U.S. Patent No. **5,178,628**) and **Smith** (U.S. Patent No. **4,513,747**).

Claims 1, 12, and 21-22: **Prasad** discloses an elongated needle body **10** that defines a longitudinal y- axis and x and z axes transverse to the y-axis, and a central shaft **12** having a first end **20** and a second needled end **14** (Figures 1A and 2A). The needled end **14** has lower and upper opposed surfaces and single side surfaces **22** extending continuously between the lower and upper surfaces and contiguous therewith, the upper surface and side surfaces intersecting to define opposed first and second side cutting edges **24** extending to a pointed tip **18**, the lower surface extending to a third cutting edge **24** defined at the intersection of the side surfaces, and the needle end having a transition area with a proximal portion having a trapezoidal transverse cross-sectional dimension being defined by having exactly one pair of parallel sides. and also a distal

portion of the transition area having a triangular transverse cross-section (the transition/trapezoidal transverse cross-section area is between the triangular cross-sections of Figures 1C and 2C and the square cross-sections of Figures 1B and 2B), and the upper surface terminating adjacent the pointed tip and the lower surface terminating proximally of the pointed tip (Figure 3).

Prasad does not disclose the transition area including a first length and the distal portion of the needle end disposed distally of the transition area including a second length, wherein the first length being longer than the second length.

Otsuka teaches a needle with a transition area **5a** having a first length and a distal portion of the needle (along **11b**) disposed distally of the transition area having a second length, wherein the first length is longer than the second length (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Prasad with a longer length transition area than the length distal to the transition area, as taught by Otsuka, to Prasad in order to prevent the needle from being displaced in the tissue in a direction generally transverse to the cutting edges (col. 7, lines 17-28).

Prasad also discloses the claimed device except for the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body and terminating at the pointed tip, and also lacks the linear cutting edge intersecting the upper planar surface at an angle ranging from about 15 to about 30 degrees relative to the longitudinal axis.

Smith teaches a third cutting edge **21** extending in oblique relation relative to the longitudinal axis of the needle body and terminating at the pointed tip and an angle of slope **d** between the cutting edge **21** and upper surface **33** that ranges from about 15 to 30 degrees relative to the longitudinal axis (Figure 3, col. 5, lines 4-9). Smith teaches that this range of angles provides ease of passage of the need through the tissue (col. 3, lines 36-38). It would have been obvious to modify Prasad with the linear cutting edge intersecting the upper planar surface at an angle ranging from 15 to about 30 degrees, as taught by Smith, in order for the needle to easily pass through tissue and also it was known in the art that providing an angle of slope determines the rate at which tissues are cut, and therefore may be altered depending on the application and the particular tissue to be cut.

Claim 2: Prasad discloses upper and lower surfaces that are substantially planar (see Figures 3-4 and abstract – the needle has a rectangular cross-section shaft).

Claims 5-7, and 14: Prasad discloses the needle having a cross-sectional dimension that defines a dimension along the z-axis corresponding to a first width of the needle end, which is at least equal to the corresponding shaft width of the central shaft, is greater than the corresponding shaft width, or a needled end defining a maximum dimension along the z-axis greater than a corresponding maximum dimension along the z-axis of the central shaft (Figure 3, col. 4, line 65 to col. 5, line 11). Although the first width of Prasad is not disclosed as not less than about 1.5 times the shaft width, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the dimension of a first width of the needle end being at least equal to a

corresponding shaft width of the central shaft, greater than a corresponding shaft width of the central shaft, as suggested by Prasad, and not less than about 1.5 times the shaft width, since it was known in the art that the needle end would produce a large cut through the tissue that reduces drag force and permits the rest of the needle to pass through easily (col. 5, lines 4-9).

Claim 10: Prasad discloses a needle body that is curved along the longitudinal axis (Figures 1A and 2A).

Claim 13: Prasad discloses the side surfaces being each substantially planar (Figures 1C and 2C).

3. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Prasad** (U.S. Patent No. **5,330,441**) in view of **Otsuka** (U.S. Patent No. **5,178,628**) and **Smith** (U.S. Patent No. **4,513,747**), as applied to Claim 6 above, and further in view of **Naslund** (U.S. Patent No. **4,133,339**).

Claims 8-9: Prasad, Otsuka, and Smith disclose the claimed device including a trapezoidal cross-sectional dimension (see above rejection for Claim 1), but lack having the cross-sectional dimension defining a dimension along an x-axis corresponding to a first height of the needle end, the first height being less than a corresponding shaft height of the central shaft, and not greater than about 0.5 times the shaft height.

Naslund teaches a needle capable of holding sutures that has a thickness ("first height") around a first portion **303**, which is perpendicular to the width (col. 3, lines 27-29), that is less than a corresponding shaft portion **307** and not greater than about 0.5

times the shaft thickness. Naslund teaches that the diminished thickness allows for a corresponding increase in the thickness, and therefore an increase in rigidity of the needle (col. 2, lines 17-21). It would have been obvious to modify Prasad, Otsuka, and Smith with the thickness dimension less than a corresponding shaft portion and not greater than about 0.5 times the shaft thickness, as taught by Naslund, because it allows an increase in the thickness of the needle and adds to the rigidity of the needle.

4. Claim 11 rejected under 35 U.S.C. 103(a) as being unpatentable over **Prasad** (U.S. Patent No. **5,330,441**) in view of **Otsuka** (U.S. Patent No. **5,178,628**) and **Smith** (U.S. Patent No. **4,513,747**), as applied to Claim 10 above, and further in view of **McGregor et al.** (U.S. Patent No. **4,524,771**).

Claim 11: Prasad, Otsuka, and Smith disclose the claimed device except for the elongated needle shaft defining an angle of curvature ranging from about 80 to about 180 degrees.

McGregor et al. discloses an elongated needle shaft **25** with an angle of curvature within the range of about 80 to about 180 degrees. McGregor et al. teaches that the curve in the needle is helpful in placing the suture by allowing the surgeon to grasp the body of the needle near its center and allows the suture to be placed at a desired depth by a controlled emergence of the needle from the tissue (col. 1, lines 9-24). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an angle of curvature ranging from about 80 to about 180 degrees to the elongated needle shaft, as taught by McGregor et al., to the combined device of Prasad,

Otsuka, and Smith in order to facilitate placing the suture in the tissue to be closed at a desired depth.

5. Claims 15-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Prasad** (U.S. Patent No. **5,330,441**) in view of **Otsuka** (U.S. Patent No. **5,178,628**) and **Munoz** (U.S. Patent No. **5,762,811**).

Claim 15: Prasad discloses an elongated needle body **10** that defines a longitudinal y- axis, and a central shaft **12** having a first end **20** and a second needled end **14** (Figures 1A and 2A). The needled end **14** has lower and upper opposed surfaces and single side surfaces **22** extending continuously between the lower and upper surfaces and contiguous therewith, the upper surface and side surfaces intersecting to define opposed first and second side cutting edges **24** extending to a pointed tip **18**, the lower surface extending to a third cutting edge **24** defined at the intersection of the side surfaces and proximal of the pointed tip, the second needled end defining a maximum dimension inclusive of the first and second cutting edges greater than a corresponding maximum dimension of the central shaft (Figure 3, col. 4, line 65 to col. 5, line 11), and the needle end having a transition area with a proximal portion having a trapezoidal transverse cross-sectional dimension inclusive of the first and second cutting edges and also a distal portion of the transition area having a triangular transverse cross-section inclusive of the first and second cutting edges (the transition/trapezoidal transverse cross-section area is between the triangular cross-sections of Figures 1C and 2C and the square cross-sections of Figures 1B and 2B), and the upper surface terminating

adjacent the pointed tip and the lower surface terminating proximally of the pointed tip (Figure 3).

Prasad does not disclose the transition area including a first length and the distal portion of the needle end disposed distally of the transition area including a second length, wherein the first length being longer than the second length.

Otsuka teaches a needle with a transition area **5a** having a first length and a distal portion of the needle (along **11b**) disposed distally of the transition area having a second length, wherein the first length is longer than the second length (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Prasad with a longer length transition area than the length distal to the transition area, as taught by Otsuka, to Prasad in order to prevent the needle from being displaced in the tissue in a direction generally transverse to the cutting edges (col. 7, lines 17-28).

Prasad discloses the claimed device except for the first and second side cutting edges being generally arcuate and the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body.

Munoz teaches single side surfaces intersecting to define opposed first and second generally arcuate side cutting edges that extend to a pointed tip and a lower surface of body portion that extends to a third cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip, and also extends in oblique relation relative to the longitudinal axis of the upper surface (Figures 5A-5C). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the

side surfaces extending to a pointed tip, as taught by Munoz, to the device of Prasad, since it was known in the art that needles should be as sharp as possible at the tip and must spread tissue out with the arcuate side surfaces in order to function properly, which is known in the art since sharper needles require less force and therefore less tissue trauma.

Munoz teaches that the cutting edge that extends in oblique relation relative to the longitudinal axis serves as an angle of slope which determines the rate at which tissues are cut, and therefore may be altered depending on the application and the tissue to be cut (Figures 5A-5C). It would have been obvious to provide side surfaces extending to a pointed tip and the lower surface extending to a cutting edge defined at the intersection of the side surfaces, which extends in oblique relation relative to the longitudinal axis, as taught by Munoz, to Prasad since it was known in the art that providing an angle of slope determines the rate at which tissues are cut, and therefore may be altered depending on the application and the particular tissue to be cut.

Claims 16-17: Prasad discloses the side surfaces each being substantially planar (Figures 1C and 2C), and the third cutting edge being substantially linear (Figure 3).

Claim 20: Prasad discloses the claimed device except for the maximum dimension of the second needled end is at least about 1.5 times the maximum dimension of the central shaft.

Although Prasad does not disclose for the maximum dimension of the second needled end is at least about 1.5 times the maximum dimension of the central shaft, it would have been obvious to one of ordinary skill in the art to modify Prasad with this

dimension since it was known in the art that the needle end would produce a large cut through the tissue that reduces drag force and permits the rest of the needle to pass through easily.

Response to Arguments

4. Applicant's arguments with respect to claims 1-2, 5-17, 20-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734
/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731